ClinicalTrials.gov Results Registration System (Data Entry Mock-up)

Guided Tour: Interactive Early Mock-up

Introduction

The ClinicalTrials.gov Results Registration System (RRS), to be implemented by September 2008, is intended to allow users to fulfill the requirements of the "basic results" provisions of Section 801 of the Food and Drug Administration Amendments Act (Pub. L.110-85). Eventually, there will be two methods of submitting data: (1) Interactive Web-based data entry of results or (2) Automated, batch upload of results data files.

This guided tour provides a step-by-step review of an *early mock-up* of the interactive Web-based RRS data entry system (available at http://prsinfo.clinicaltrials.gov/rrs-mockup-intro.html). It illustrates key features of the mock-up. The mock-up itself is **not** final or comprehensive.

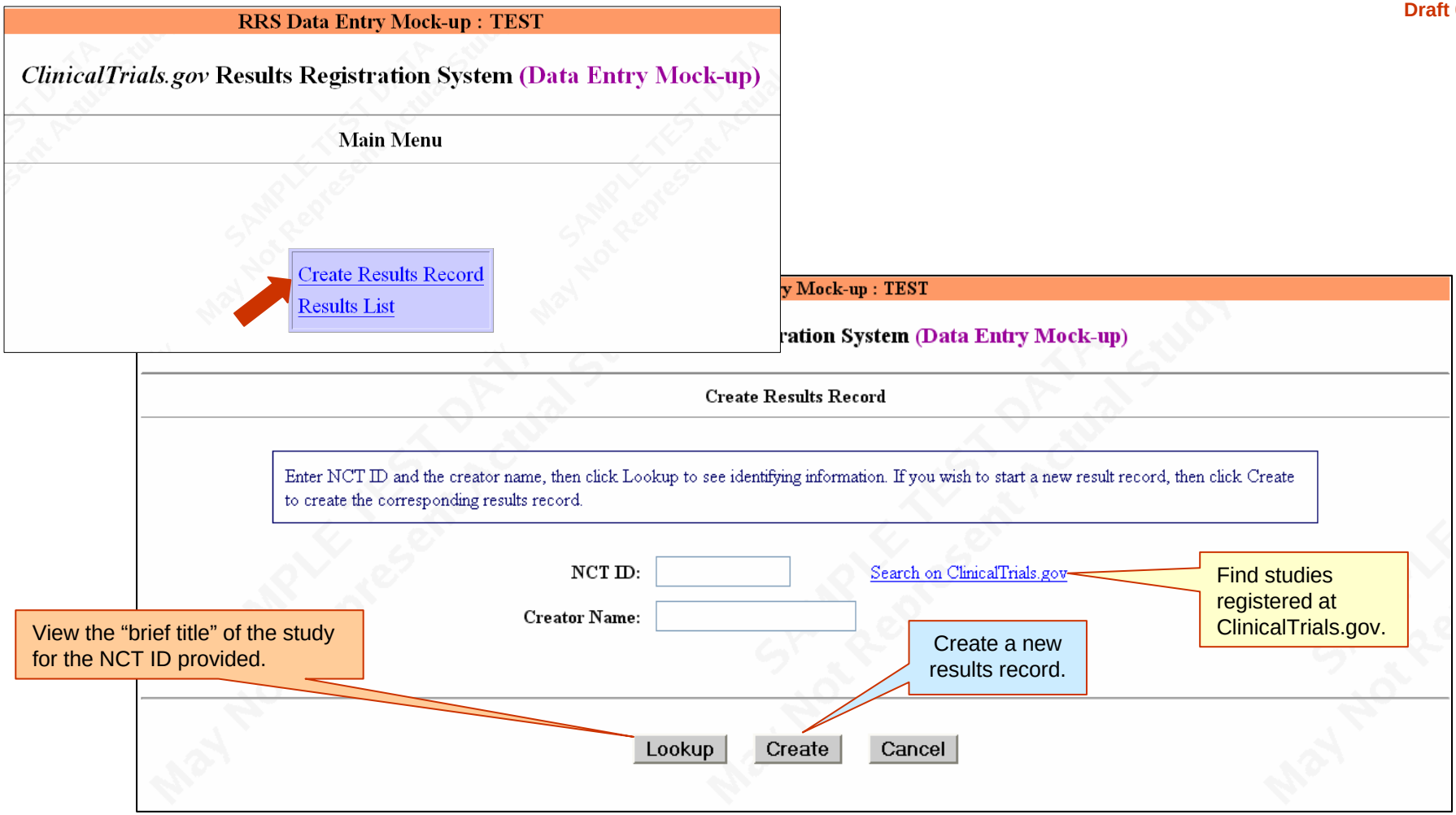
A goal of this early mock-up is to inform members of the public of our current thinking on the types and organization of data for submission of "basic results," including data items and dropdown menu choices. There are two ways to explore the site:

- Click through the two fixed (read-only) sample results records
- Create your own "practice" result record (Note: Practice records are accessible to other current users of the site. All practice records will be deleted nightly)

Comments and feedback on the basic structure of the results information we are collecting will be considered during the iterative development of the system. Please do **not** comment on the user interface or usability, as we will address these issues in later iterations. Submit all comments using the form at http://prsinfo.clinicaltrials.gov/rrs-comments.html.

Notes on the Interactive Early Mock-up

1. Requirements for basic results information have not been determined. The presence of a data item in this interactive early mock-up does not necessarily imply that it will be required.
2. This mock-up does not address the public display of results. The public display will be the subject of a future posting.

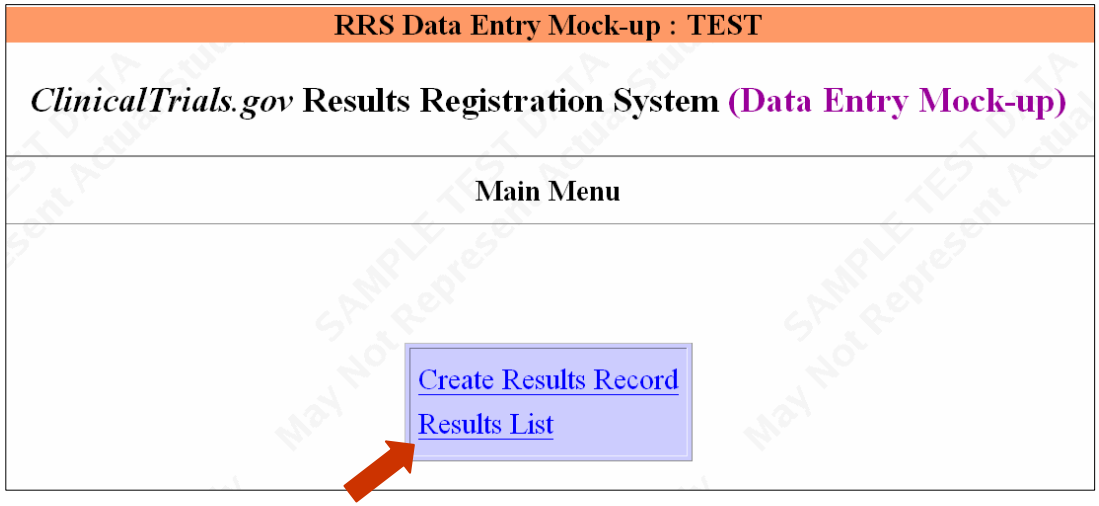


Creating a New Results Record

To create a "practice" results record in the mock-up, click on "Create Results Record." In the actual system, this step will be conducted through your usual ClinicalTrials.gov Protocol Registration System (PRS) account.

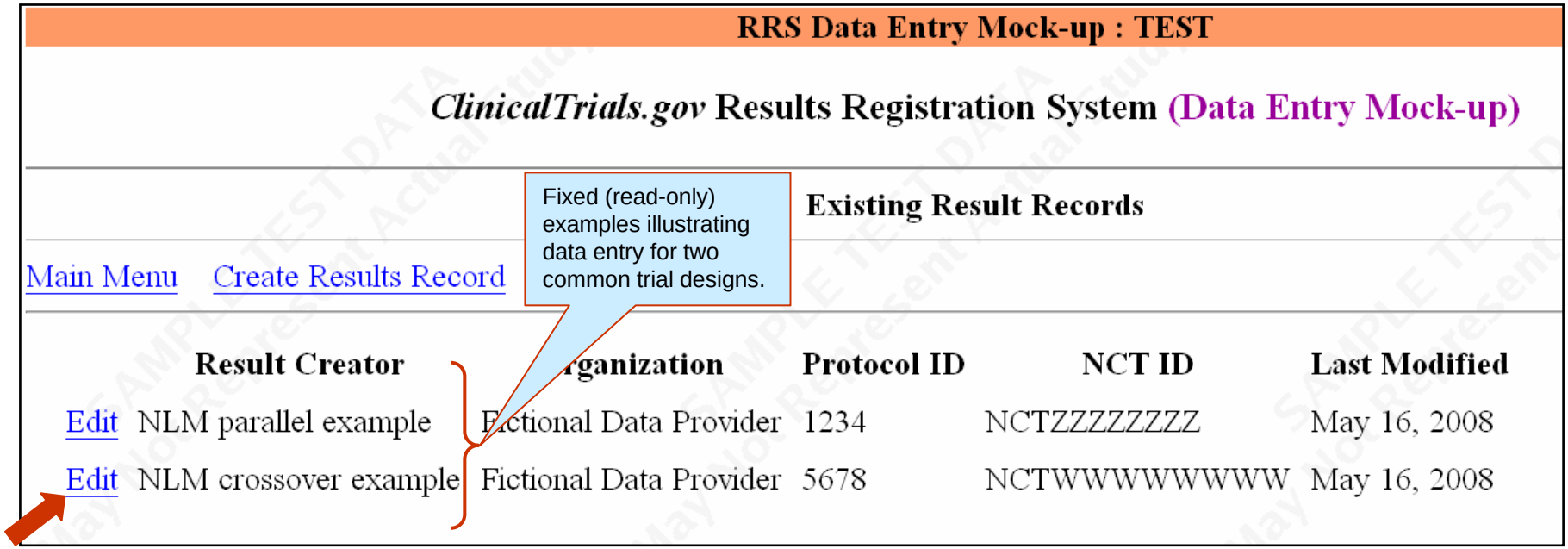
The Create Results Record page allows users to generate a practice results record in this mock-up. Click "Create" after entering a valid NCT number from the ClinicalTrials.gov registry and any text in the "Creator Name" field.

Note that practice records are visible and modifiable by other current users. In the actual system, users will only have access to those records for which they are the owner. Also, all "practice" records will be deleted each night.



Exploring an Existing Results Record

To explore a results record in the mock-up, click on “Results List.” In the actual system, this step will be conducted through your usual PRS account.



Exploring Existing Results Records

This page provides a menu to access results records available in the mock-up. The list includes two fixed (read only) fictitious examples of results records and any records entered by users on that day. This page is not intended for comment and is simply a menu to access examples. All results records must have been registered in ClinicalTrials.gov, thus each results record identifier ("Protocol ID") will have a corresponding unique registration identifier ("NCT ID").

The user can click "edit" next to a record to review or enter information. For example, clicking "edit" next to "NLM crossover example" will take the user to the "edit results record" page for this study.

RRS Data Entry Mock-up : TEST

ClinicalTrials.gov Results Registration System (Data Entry Mock-up)

Edit Results Record

Main Menu Results List

Information Provided By: Fictional Data Provider
Unique Protocol ID: 5678
Brief Title: A Sample Study with a Crossover Design
NCT ID: NCTWWWWWWWW

Edit	**Result Point of Contact:**	[To Be Developed] Name/Official Title: Organization: Phone: Ext: Email:
	Certain Agreement:	[To Be Developed]
Edit	**Participant Flow:**	Trial Period:**Period1** Trial Period:**Period 2** Trial Period:**Period 3**
Edit	**Baseline Characteristics:**	• **Age** [Time Frame: Enrollment] • **Age Categories** [Time Frame: Enrollment] • **Gender** [Time Frame: Enrollment] • **Race** [Time Frame: Enrollment] • **Ethnicity** [Time Frame: Enrollment] • **Region of Enrollment** [Time Frame: Enrollment] • **Menopausal Status** [Time Frame: Enrollment] • **Hot Flashes** [Time Frame: Enrollment]
Edit	**Limitations and Caveats:**	[To Be Developed]
Edit	**Outcome Measures:**	• **Primary Measure:** (DATA) Change in hot flash score [Time Frame: 12 weeks]

Data automatically imported (pre-populated) from the corresponding ClinicalTrials.gov registration record, NCTWWWWWWWW).

Placeholders for an FDAAA 801 "basic results" information.

"Period 1" is pre-listed by system. Additional discrete "periods" may be added, as needed. Two additional periods have been entered for this example.

The first six baseline characteristics are pre-listed by the system. Two additional characteristics have been entered for this example.

Pre-populated from registration record.

Edit Results Record Page - Overview of data in results record pre-populated from the fictitious ClinicalTrials.gov registry record, NCTWWWWWWWW. The user can enter data by clicking the "edit" next to "Participant Flow." In the actual system, it will be possible to complete modules in any sequence.

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ClinicalTrials.gov **Results Registration System (**

Participant Flow for NCTWWWWWWWW

OK Add New Period Edit Comparison Groups

User-specified "comparison groups." These columns will default to "arms," but may be modified as appropriate.

If relevant, please describe how and why the number of subjects enrolled differs from the number to start the first period.

70 women between the ages of 40 and 65 who were having hot flashes were recruited for the study at family practice clinics in Washington, DC. 8 were excluded from the study due to concomitant conditions.

Period	Milestone		placebo then drug 10mg	drug 10mg then placebo
Edit Period1	Started Period	Number subjects started period	33	29
		Comments	Period one is a -week re-treatment eriod to assess baseline measurements.	Period one is a 1-week pre-treatment period to assess baseline measurements.
	Completed	Number subjects completed period	29	24
		Number subjects not completing period	4	4
		Reason: Other	4	4
		Reason: Adverse Events		
		Comments (Describe other reasons in comments.)	Not specified	Not specified

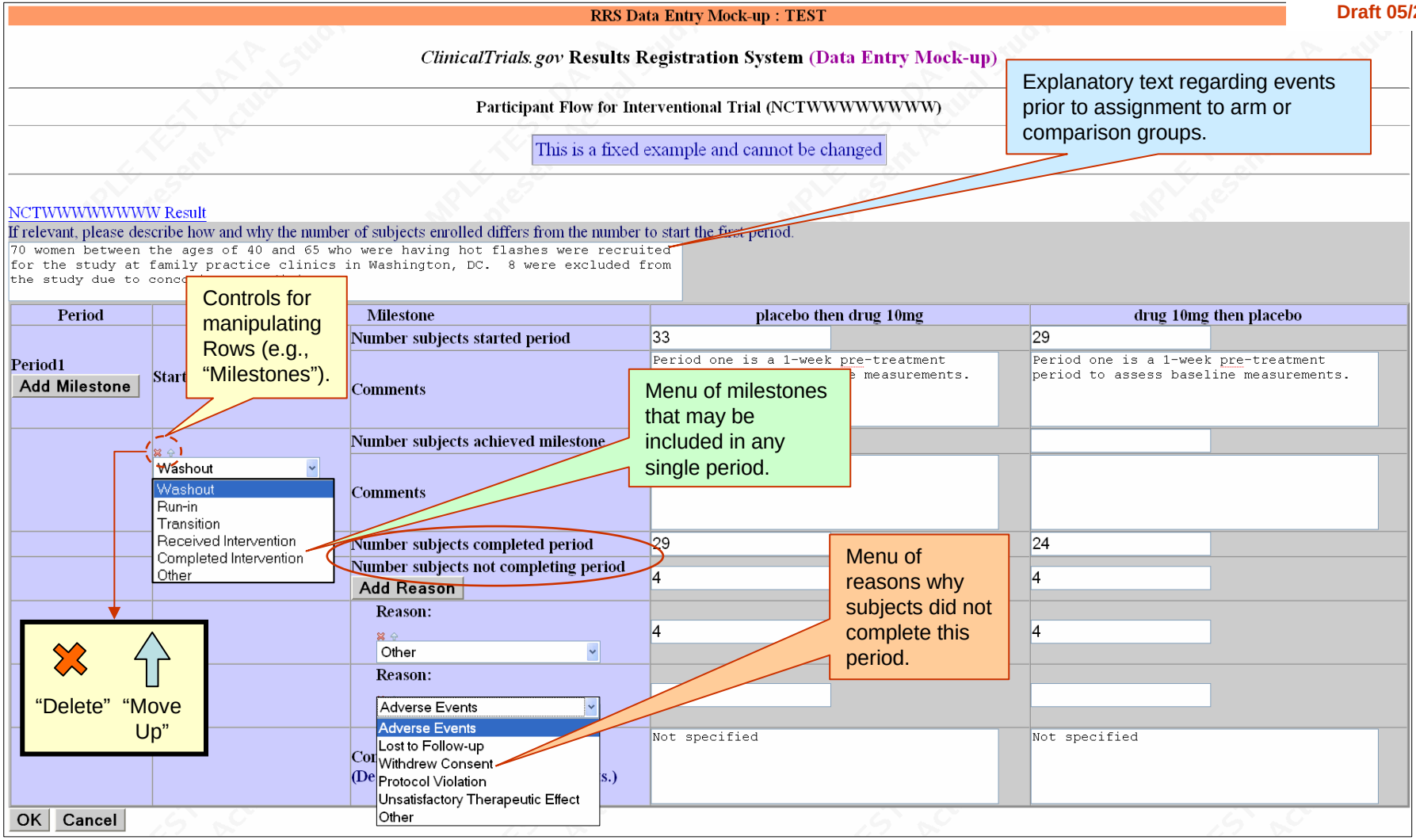
Any number of "milestones" may be reported for a period, as needed.

Participant Flow

Like a CONSORT flow diagram*, this page is used to enter information about the progress of subjects through the different "periods" of a study, but in a tabular format rather than a diagram.

Each "period" always begins and ends with— (1) Started Period and (2) Completed Period, respectively. Many studies will have just one period, though some, for example, a crossover study, might have two or more periods.

* See figure on p. 660: Moher D et al. *Ann Intern Med*. 2001;134:657-62.



Participant Flow (continued)

Milestones may be added to a period and described using the dropdown menu (e.g., "washout"). Free-text fields facilitate annotation of each milestone.

The Completed Period consists of two pre-listed milestones: (1) "Number subjects completed period" and (2) "Number subjects not completing period." The latter milestone may be further subdivided into different categories of reasons why subjects did not complete the period by using the dropdown menu (e.g., "adverse events"). A comment section is provided for additional reasons.

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Baseline Measures for NCTWWWWWWWW

This is a fixed example and cannot be changed

OK Add New Baseline Measure Edit Comparison Groups

Edit	Age [TimeFrame: Enrollment] [MeasureUnit: Years]	Total		drug 10mg to placebo		placebo to drug 10mg	
		median	full range	median	full range	median	full range
	Age	53.9	36.6 to 77.1	52.3	41.1 to 77.1	56.7	36.6 to 77.0

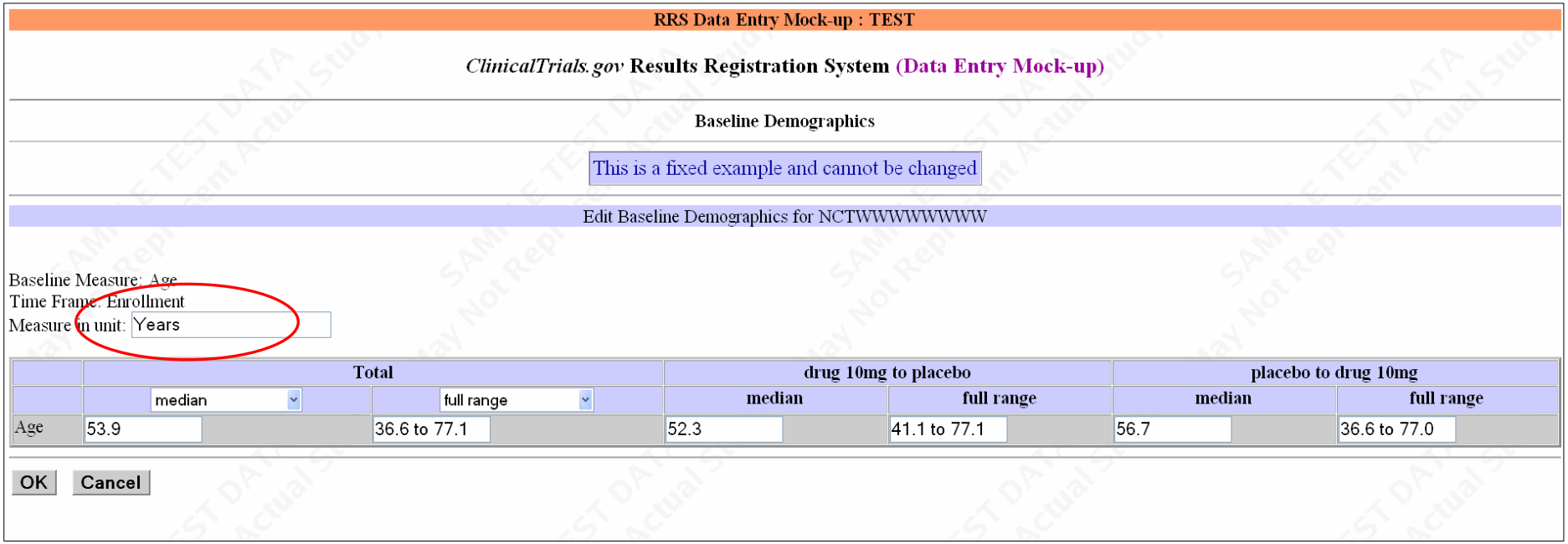
Edit	Age Categories [TimeFrame: Enrollment] [MeasureUnit: Number of Subjects]	Total	drug 10mg to placebo	placebo to drug 10mg
		number	number	number
	>=65 years			
	<=18 years			

Edit	Gender [TimeFrame: Enrollment] [MeasureUnit: Number of Subjects]	Total	drug 10mg to placebo	placebo to drug 10mg
		number	number	number
	Female	62	33	29
	Male			
	Other			
	Unspecified / Unknown			

Baseline Measures

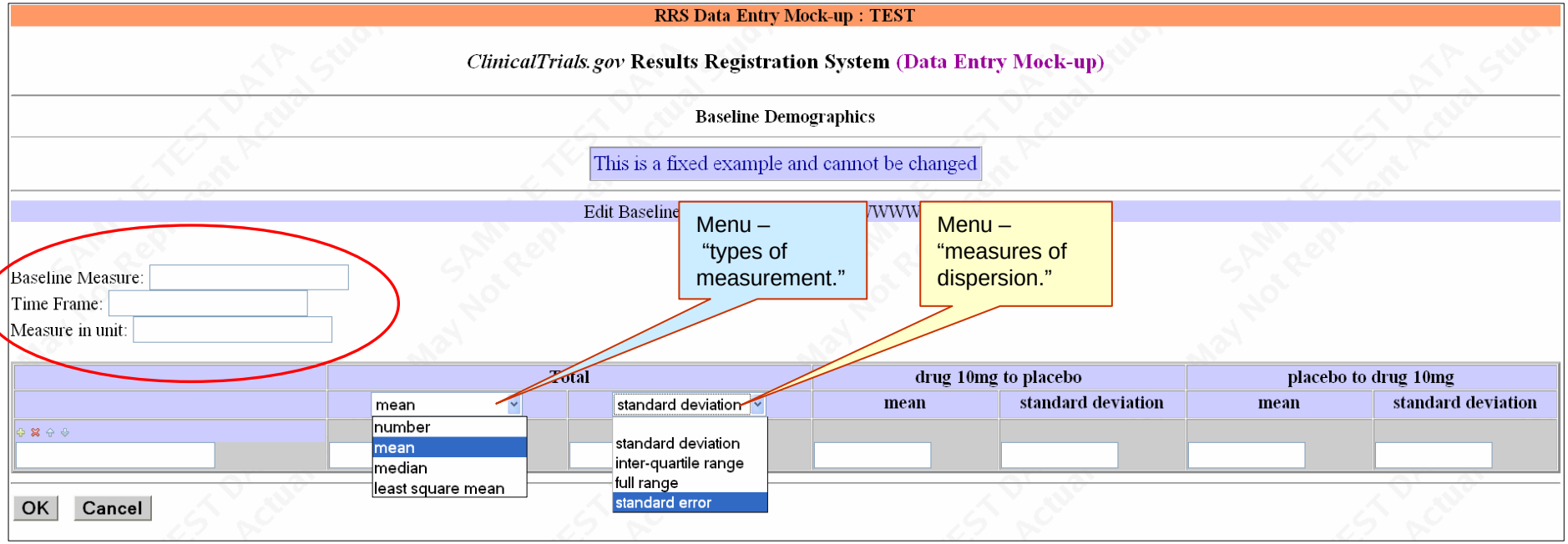
This page is an overview of baseline measures for a results record. Data for each baseline measure are entered as a table. Tables can be customized by the user to describe the characteristics of the subjects in a trial. There are columns for groups of participants: “Total,” and one column for each arm. Arm information will be pre-populated from the registry. However, if it is not available or is not appropriate for the particular trial, then column headings can be entered by the user. The column heading can be edited by selecting “Edit Comparison Groups.”

Each row will represent one baseline characteristic. Commonly used characteristics are pre-listed and include Age (as a continuous variable), Age (as a categorical variable), Gender, Race, Ethnicity, and Region of Enrollment. Any tables and rows appropriate to a study may be used. However, specific requirements have not been determined.



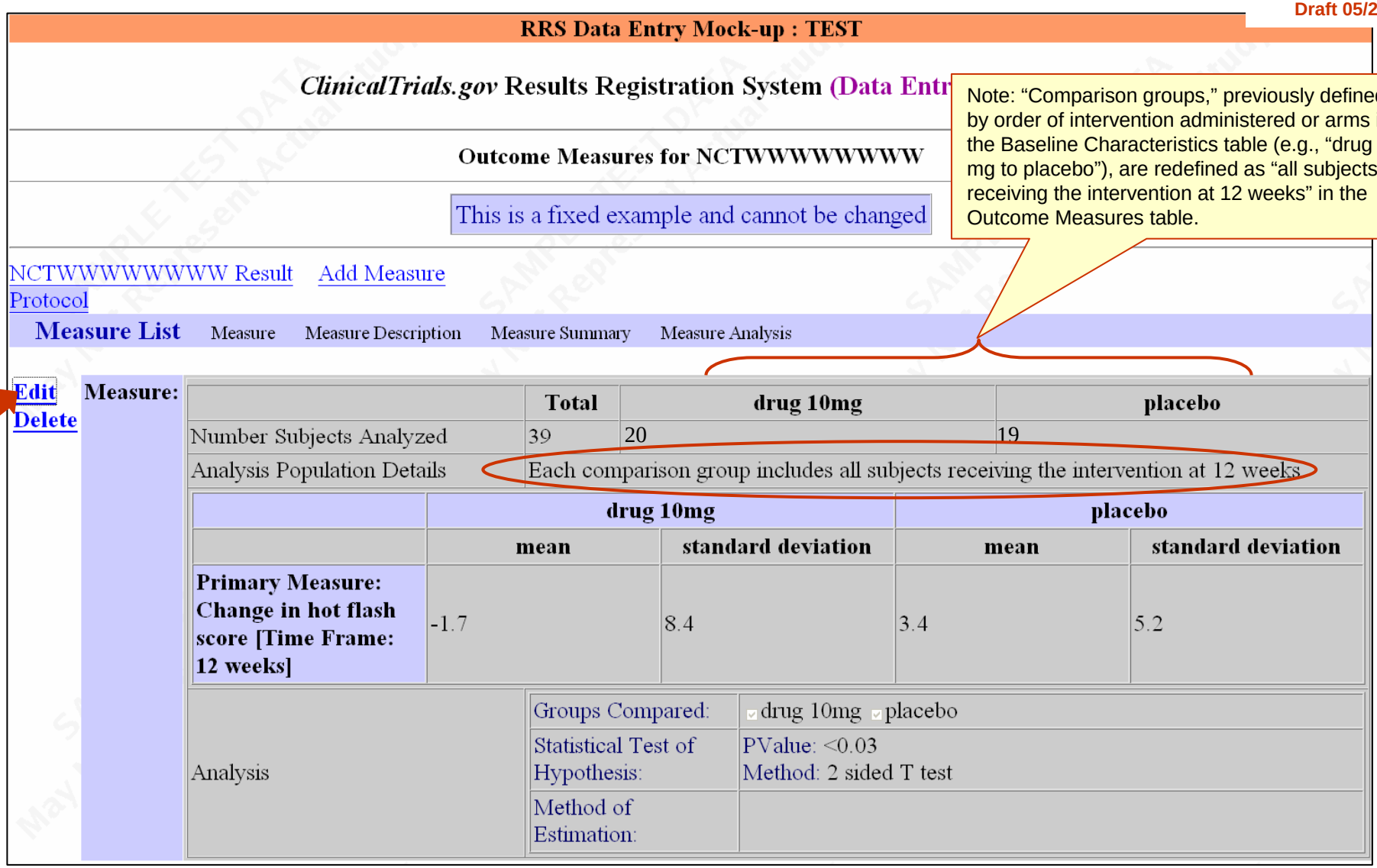
Edit Baseline Demographics – Pre-set Baseline Measure

This page demonstrates the pre-set table for Age (as a continuous variable). Although Age is listed with a unit of "years," the unit can be changed to one that is more appropriate for the study (e.g., months).



Edit Baseline Demographics – New Baseline Measure

Users can "Add New Baseline Measure(s)" from the Baseline Measures page (*page 8*) to enter other measures of relevance to the particular study. The user can enter descriptive information about the measure: the name of the baseline measure, time frame and the units of the measure. Users can also indicate the type of measurement (e.g., mean, median, etc), a measure of dispersion (if a continuous measure) and names of categories (if a categorical measure). The user can then enter the data into the appropriate cells of the newly constructed table.



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ClinicalTrials.gov Results Registration System (Data Entr

Note: "Comparison groups," previously defined by order of intervention administered or arms in the Baseline Characteristics table (e.g., "drug 10 mg to placebo"), are redefined as "all subjects receiving the intervention at 12 weeks" in the Outcome Measures table.

Outcome Measures for NCTWWWWWWWW

This is a fixed example and cannot be changed

NCTWWWWWWWW Result Add Measure
Protocol

Measure List Measure Measure Description Measure Summary Measure Analysis

Edit
Delete

Measure:

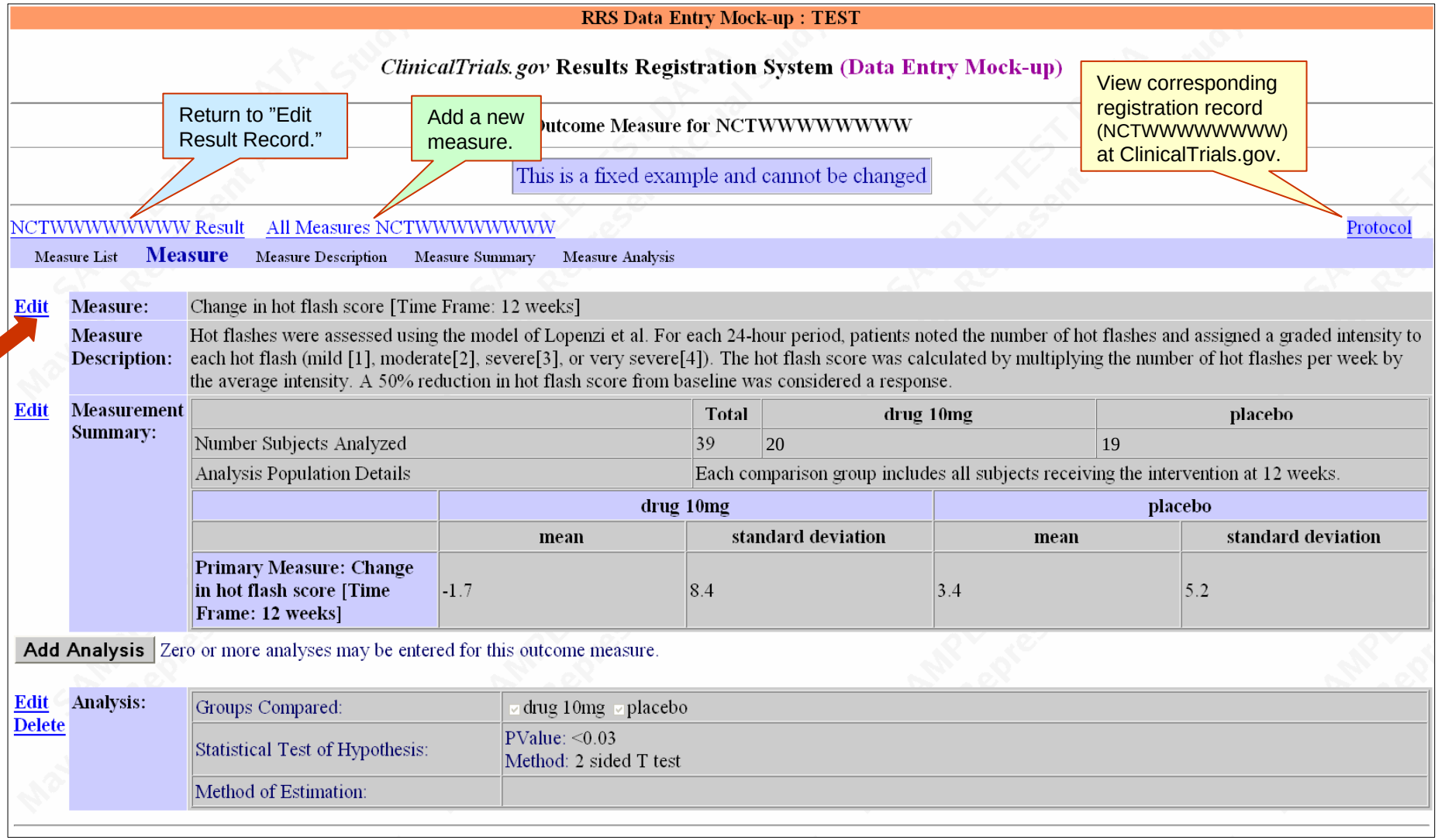
	Total	drug 10mg	placebo
Number Subjects Analyzed	39	20	19
Analysis Population Details	Each comparison group includes all subjects receiving the intervention at 12 weeks		

	drug 10mg		placebo	
	mean	standard deviation	mean	standard deviation
Primary Measure: Change in hot flash score [Time Frame: 12 weeks]	-1.7	8.4	3.4	5.2

Analysis	Groups Compared:	drug 10mg, placebo
	Statistical Test of Hypothesis:	PValue: <0.03 Method: 2 sided T test
	Method of Estimation:	

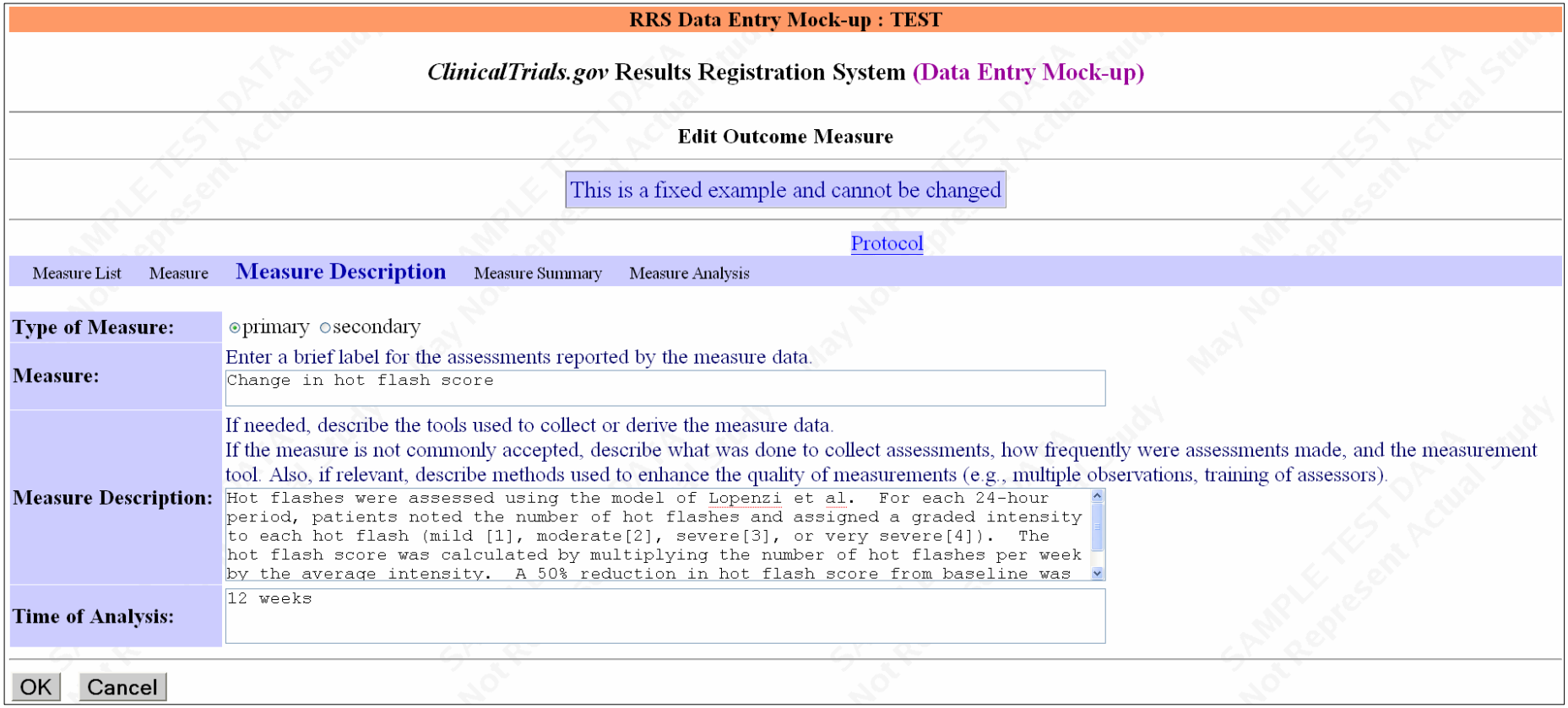
Outcome Measure List

This page is an overview of the primary and secondary outcome measures including information describing the measure and analysis of the measure. The primary and secondary outcome measures are pre-populated from the registry record and may be edited. First, a user may want to edit information relating to the measure itself.



Outcome Measure

This page provides users with a menu to edit a specific measure, including information related to the statistical analysis. The user can select "edit" to navigate to the next data entry screen.



Edit Outcome Measure

This page includes pre-populated information from the registry for the type, measure, and time of analysis. The measure can be edited and a detailed description of how the measure was assessed can be provided (e.g., a description of the validated instrument utilized for assessment). The time of analysis can also be edited, if necessary.

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Outcome Measure for NCTWWWWWWWW

This is a fixed example and cannot be changed

NCTWWWWWWWW Result | All Measures NCTWWWWWWWW | Protocol

Measure List | **Measure** | Measure Description | Measure Summary | Measure Analysis

Edit **Measure:** Change in hot flash score [Time Frame: 12 weeks]

Measure Description: Hot flashes were assessed using the model of Lopenzi et al. For each 24-hour period, patients noted the number of hot flashes and assigned a graded intensity to each hot flash (mild [1], moderate[2], severe[3], or very severe[4]). The hot flash score was calculated by multiplying the number of hot flashes per week by the average intensity. A 50% reduction in hot flash score from baseline was considered a response.

Edit **Measurement Summary:**

	Total	drug 10mg	placebo
Number Subjects Analyzed	39	20	19
Analysis Population Details	Each comparison group includes all subjects receiving the intervention at 12 weeks.		

	drug 10mg		placebo	
	mean	standard deviation	mean	standard deviation
Primary Measure: Change in hot flash score [Time Frame: 12 weeks]	-1.7	8.4	3.4	5.2

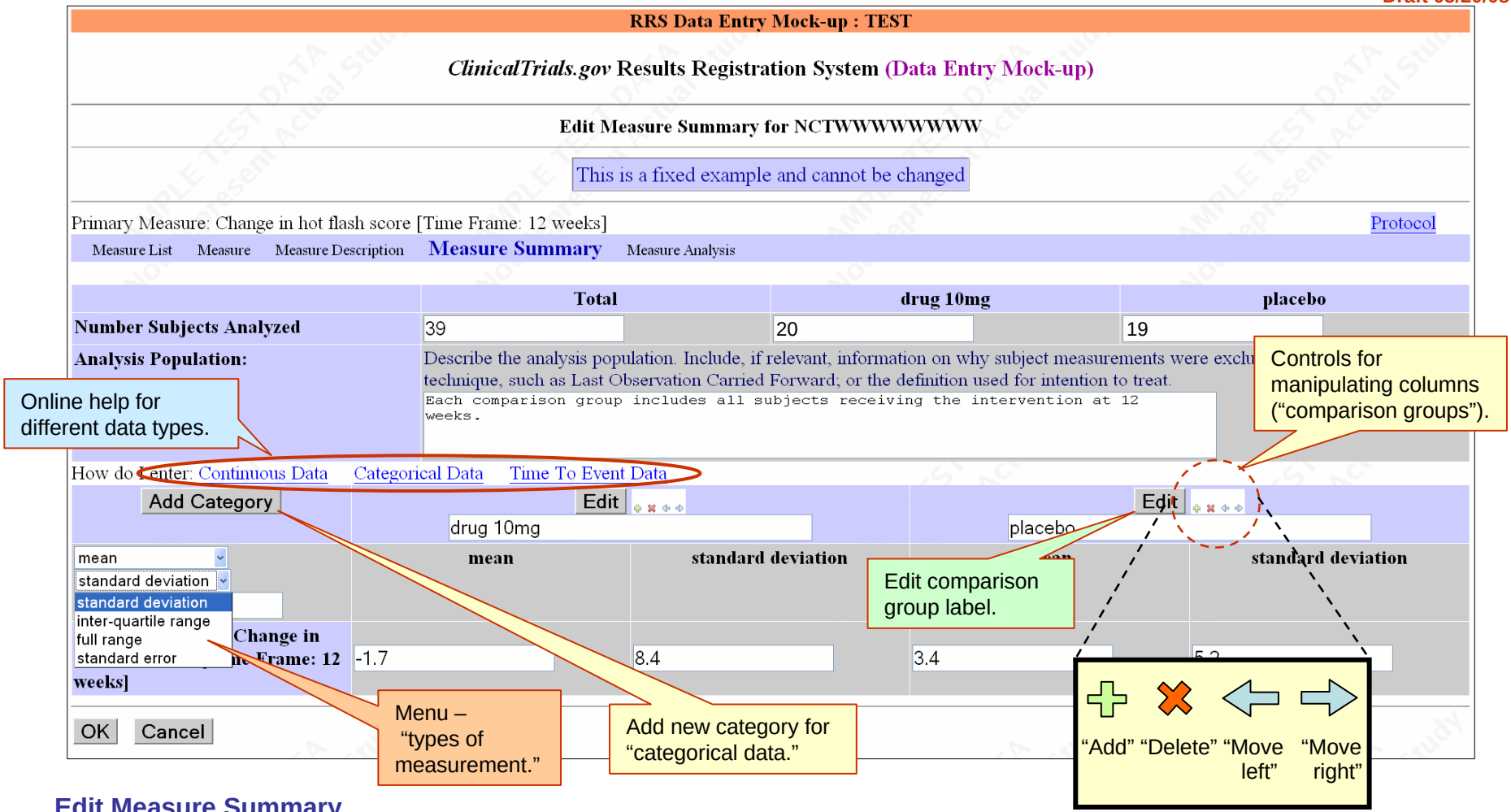
Add Analysis Zero or more analyses may be entered for this outcome measure.

Edit Delete **Analysis:**

Groups Compared:	☑ drug 10mg ☑ placebo
Statistical Test of Hypothesis:	PValue: <0.03 Method: 2 sided T test
Method of Estimation:	

Outcome Measure

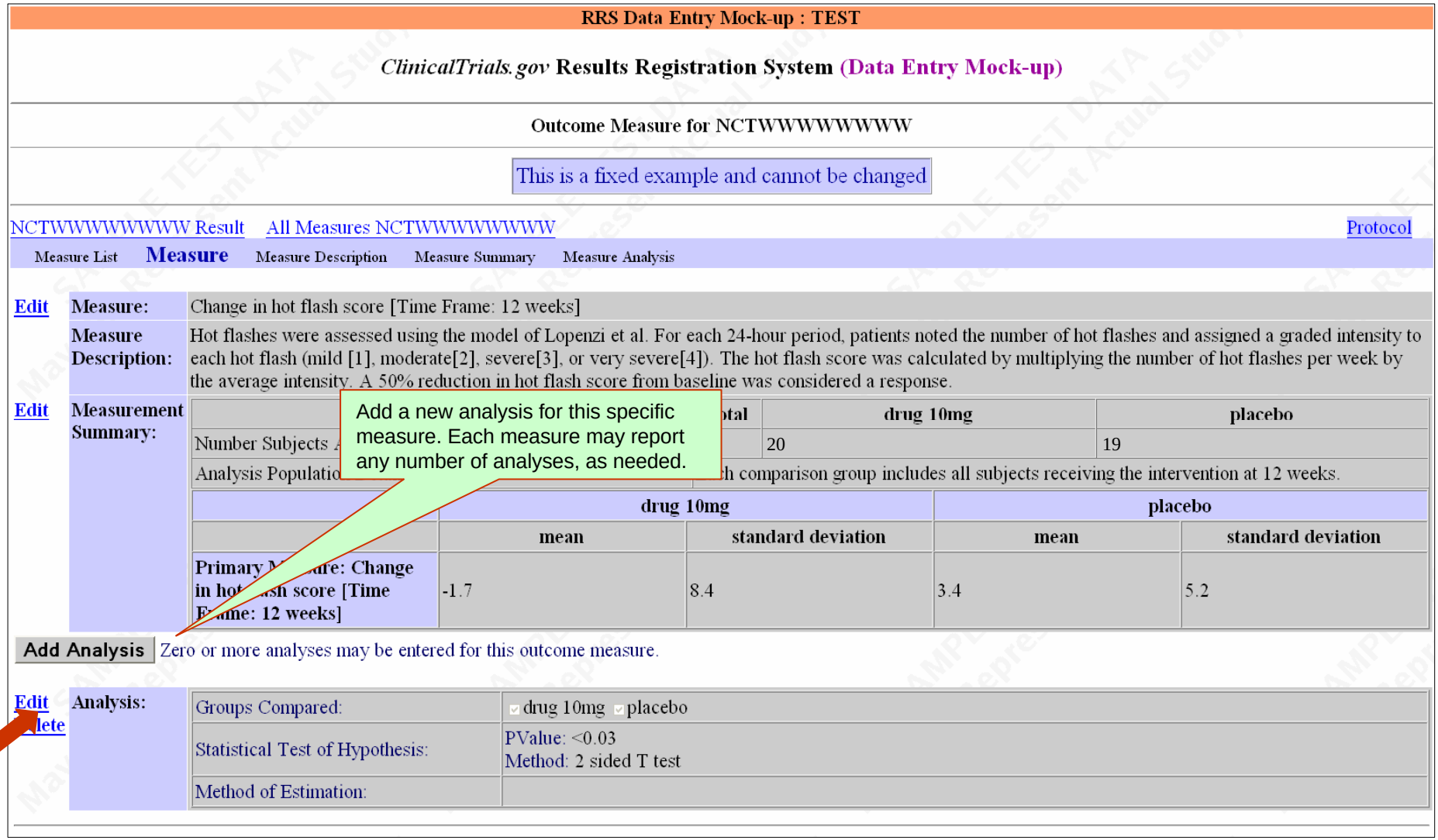
After completing the Edit Outcome Measure page, the user is returned to the menu page that allows for editing measure and analysis information. The user may then edit relevant summary information for the measure by selecting “edit” (next to “Measurement Summary”).



Edit Measure Summary

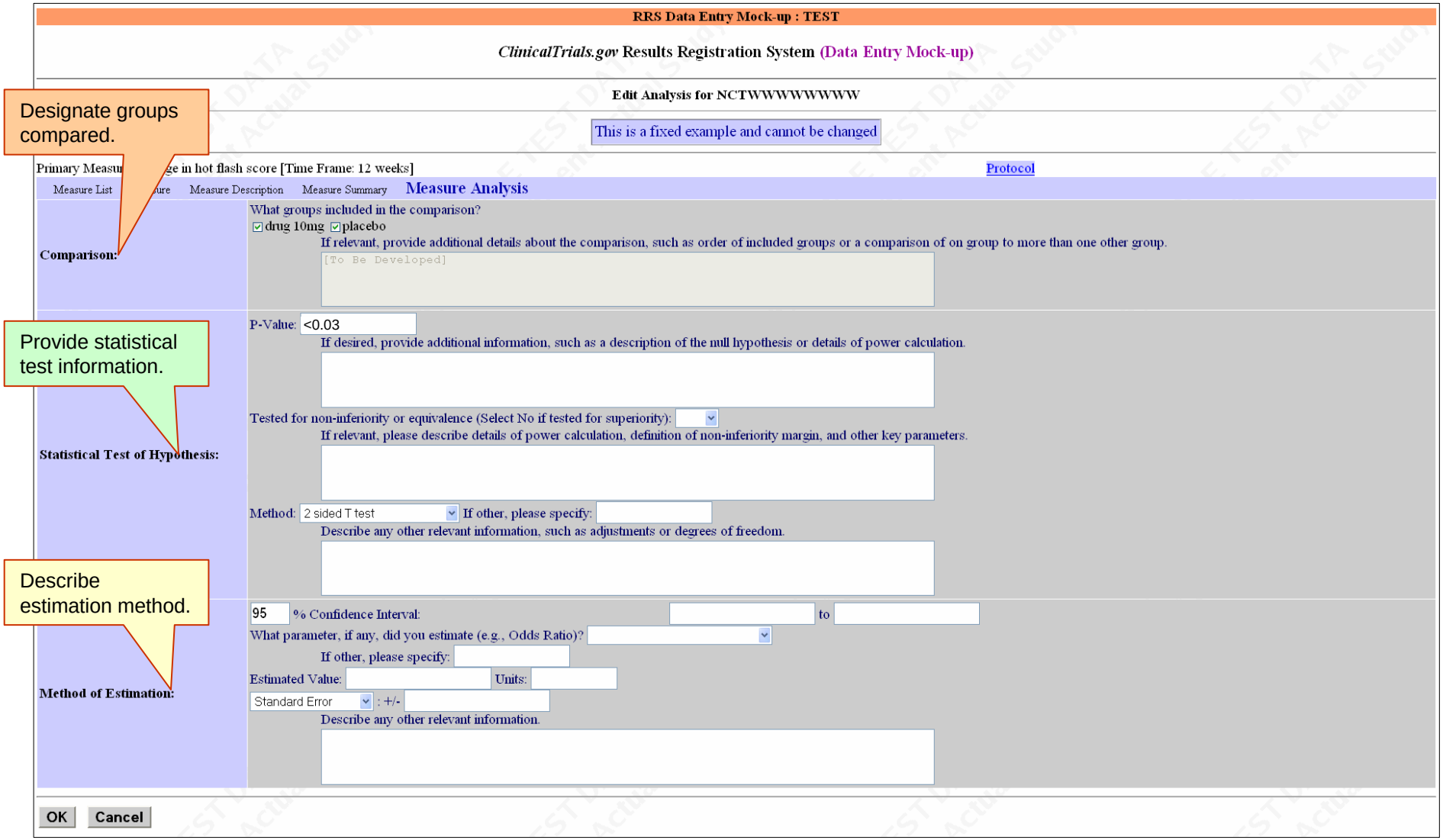
This page allows users to specify the arms/groups that were compared in the analysis. The comparison groups may be different than the arms of the study. The arms designated in the registry will be the default display, however these groups (columns) can be edited by changing the labels and adding or deleting groups (columns) in order to reflect the analysis population. Any additional information related to the population analyzed can also be provided as free text. The units of measurement, values for each cell, and a measure of dispersion can be provided, as appropriate.

After the measure summary page is completed, the user can select “OK” and return to the Outcome Measure page to “Add Analysis.” The number of analyses that are entered for each outcome measure is determined by the user.



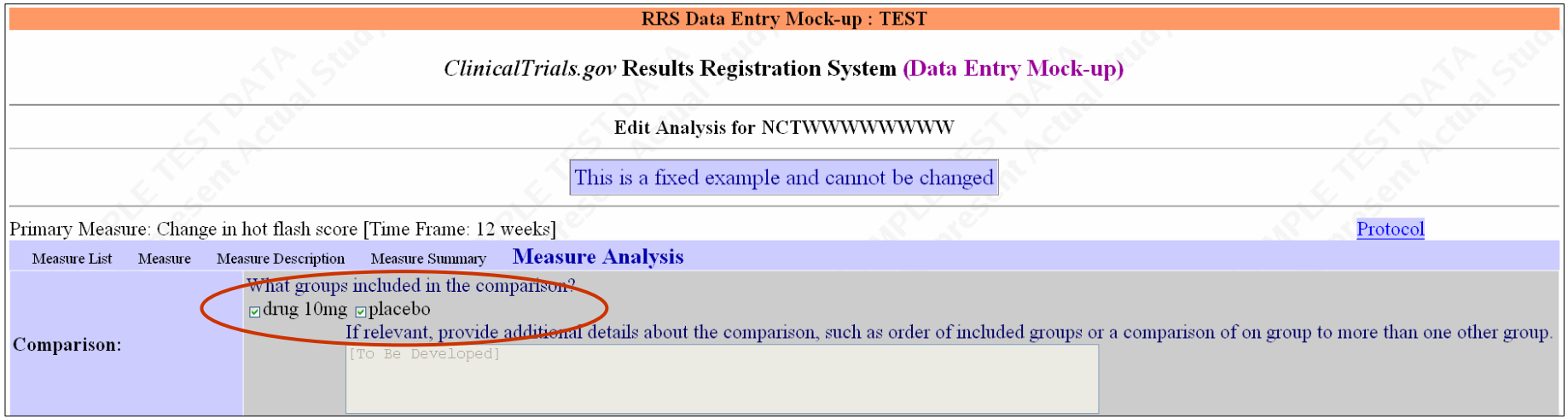
Outcome Measure

After completing the Edit Measure Summary page, the user is returned to the menu page that allows for editing measure and analysis information. The user may then edit relevant analysis information by selecting “Edit” next to “Analysis” to navigate to the next data entry screen.



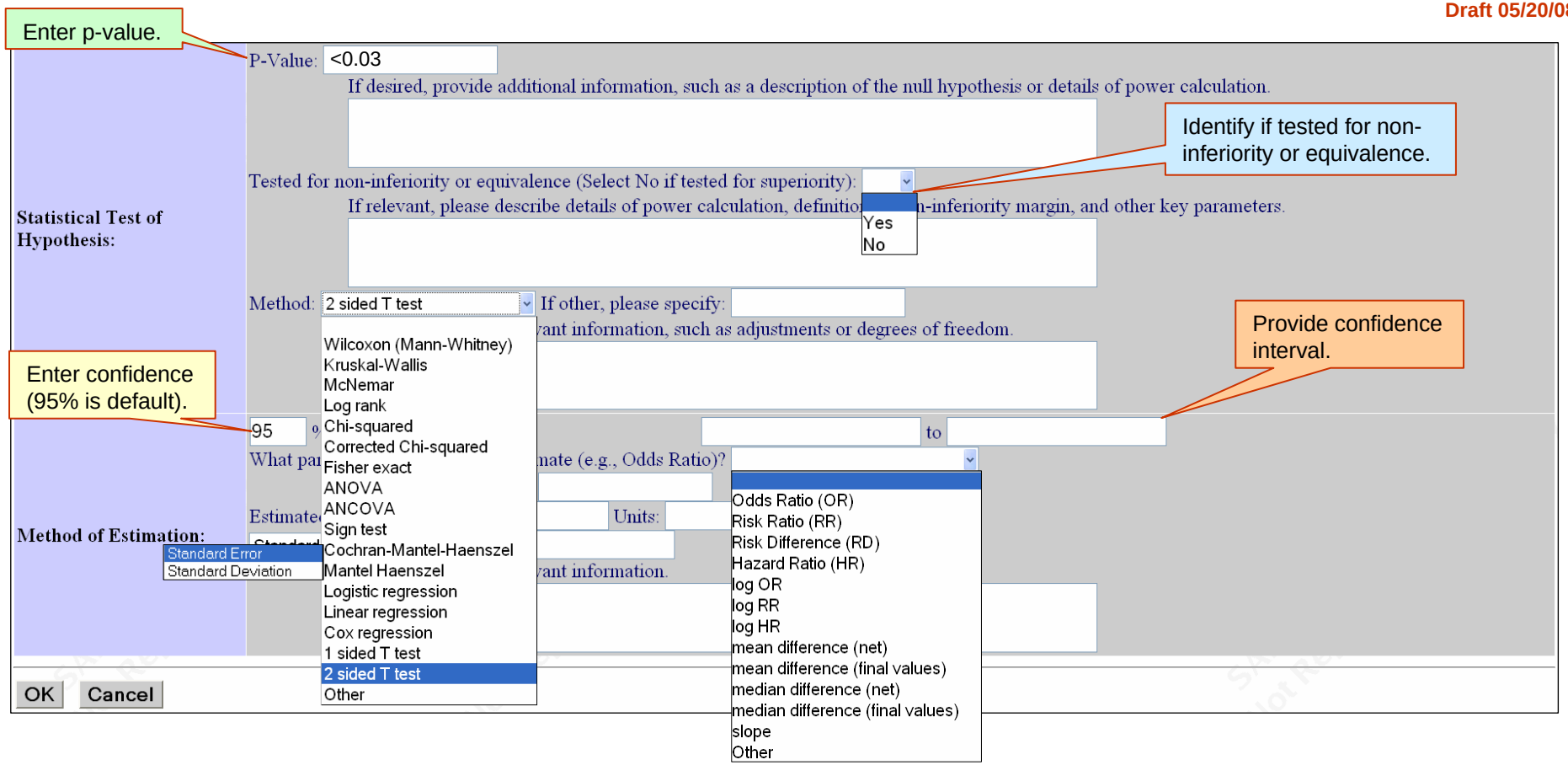
Edit Analysis

The analysis is comprised of three basic categories of information: designation of the groups (arms) being compared, statistical test information and the method of estimation.



Edit Analysis - Comparison

The user will be asked what comparison they are reporting. If the trial has two comparison groups, then both boxes should be checked. If there are more than two groups, the user should click those groups that are used in the comparison.



Edit Analysis Page – Statistical Test and Method of Estimation

The user can enter a p-value, if desired. If a p-value is entered, the user should use the pull down menu to select the name of the statistical test used. The user should also use the pull down menu to indicate if the analysis conducted is a test of non-inferiority or equivalence. Free text boxes provide space to comment on specific aspects of the analyses, as noted. The user can then enter a confidence interval, if desired. 95% is provided as the default confidence interval, however this can be edited. If a confidence interval is entered, the user should use the pull down menu to select the method of estimation used. This section includes places for noting the interval and for providing other relevant comments.